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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,752	10/19/2001	Reinhold Schmieding	P/1493-443	6145

24998 7590 03/21/2006

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EXAMINER

NAJARIAN, LENA

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,752

Applicant(s)

SCHMIEDING, REINHOLD

Examiner

Lena Najarian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-17 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the specifications": claim 1, lines 4-5.

(ii) "the delivery": claim 2, lines 2 and 3, claim 8, line 3, and claim 14, line 3.

(iii) Claims 3-7 incorporate the deficiencies of claim 1, through dependency, and are also rejected.

(iv) Claims 9-13 incorporate the deficiencies of claim 8, through dependency, and are also rejected.

(v) Claims 15-17 incorporate the deficiencies of claim 14, and are also rejected.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Referring to claim 1, Alten discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising:

customizing an allograft to a predetermined surgical procedure (abstract and col. 1, lines 45-62 of Alten).

Alten does not disclose loaning graft specific surgical instrumentation to match the specifications of the allograft and the procedure.

AORN discloses loaning surgical instrumentation to match the specific instruments needed (p. 1062-1063 of AORN Journal).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of AORN within Alten. The motivation for doing so would have been for small facilities to save space (p. 1062 of AORN).

(B) Referring to claim 7, Alten does not disclose arranging for the return of the surgical instrumentation after performance of the procedure.

AORN discloses arranging for the return of the surgical instrumentation after performance of the procedure (p. 1062-1063 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of AORN within Alten. The motivation for doing so would have been to return the borrowed instruments to the outside party (p. 1062 of AORN).

6. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning") in view of Tubo et al. (5,040,677), and further in view of Hamada (US 6,425,920 B1).

(A) Referring to claim 2, Alten and AORN do not disclose coordinating the delivery of the allograft to a medical facility at which the surgical procedure is to be performed with the delivery of the surgical instrumentation.

Tubo discloses delivering the allograft to a medical facility at which the surgical procedure is to be performed (col. 1, lines 27-29 of Tubo).

Hamada discloses coordinating the allograft and the surgical instrumentation to be compatible (abstract and col. 1, lines 9-20 of Hamada).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Tubo and Hamada within Alten and AORN. The motivation for doing so would have been for direct delivery (col. 1, lines 27-29 of Tubo) and to increase the safety and accuracy of the procedure (col. 1, lines 9-20 of Hamada).

(B) Referring to claim 3, Alten discloses wherein the allograft is harvested at a tissue bank (abstract of Alten).

Alten and AORN do not disclose that the allograft is delivered directly to the medical facility.

Tubo discloses that the allograft is delivered directly to the medical facility (col. 1, lines 27-29 of Tubo).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Tubo within Alten and AORN. The motivation for doing so would have been for the grafts to be ready for application to the patient (col. 1, lines 27-29 of Tubo).

7. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning"), and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 4, Alten and AORN do not disclose training operating personnel in the use of the instruments and skills to perform the surgical procedure.

Ramshaw discloses training operating personnel in the use of the instruments and skills to perform the surgical procedure (col. 2, lines 39-41 and col. 8, lines 65-67 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Ramshaw within Alten and AORN. The motivation for doing so would have been to provide interactive training (col. 1, lines 7-10 of Ramshaw).

(B) Referring to claim 5, Alten and AORN do not disclose providing technical support during the procedure.

Ramshaw discloses providing technical support during the procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Ramshaw within Alten and AORN. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(C) Referring to claim 6, Alten and AORN do not disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Ramshaw within Alten and AORN. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

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8. Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US 6,425,920 B1) in view of Tubo et al. (5,040,677), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Referring to claim 8, Hamada discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Hamada):

a customized allograft for a predetermined surgical procedure and customizing a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure (col. 1, lines 9-20 of Hamada).

Hamada does not disclose arranging for the delivery of the allograft.

Tubo discloses arranging for the delivery of the allograft (col. 1, lines 27-29 of Tubo).

Hamada does not disclose wherein the customized surgical instrumentation kit is loaned to the customer for the performance of the surgical procedure.

AORN discloses wherein the customized surgical instrumentation kit is loaned to the customer for the performance of the surgical procedure (p. 1062 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Tubo and AORN within Hamada. The motivation for doing so would have been for direct delivery (col. 1, lines 27-29 of Tubo) and for small facilities to save space (p. 1062 of AORN).

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(B) Referring to claim 13, Hamada and Tubo do not disclose arranging for the return of the customized surgical instrumentation kit after performance of the surgical procedure.

AORN discloses arranging for the return of the surgical instrumentation after performance of the procedure (p. 1062-1063 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of AORN within Hamada and Tubo. The motivation for doing so would have been to return the borrowed instruments back to the outside party (p. 1062 of AORN).

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US 6,425,920 B1) in view of Tubo et al. (5,040,677), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning") and Alten (4,852,554).

(A) Referring to claim 9, Hamada does not disclose wherein the allograft is harvested at a tissue bank and delivered directly to a medical facility at which the surgical procedure is to be performed.

Tubo discloses wherein the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed (col. 1, lines 27-29 of Tubo).

Tubo and AORN do not disclose wherein the allograft is harvested at a tissue bank.

Alten discloses wherein the allograft is harvested at a tissue bank (abstract of Alten)

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Tubo and Alten within Hamada and AORN. The motivation for doing so would have been for the grafts to be ready for application to the patient (col. 1, lines 27-29 of Tubo) and to ensure that the allograft is free of disease.

10. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US 6,425,920 B1) in view of Tubo et al. (5,040,677), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning") and Ramshaw et al. (5,791,907).

(A) Referring to claim 10, Hamada, Tubo, and AORN do not disclose prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Ramshaw discloses prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (col. 2, lines 39-41 and col. 8, lines 65-67 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Ramshaw within Hamada, Tubo, and AORN. The motivation for doing so would have been to provide interactive training (col. 1, lines 7-10 of Ramshaw).

(B) Referring to claim 11, Hamada, Tubo, and AORN do not disclose providing technical support to operating personnel before and/or during the performance of the procedure.

Ramshaw discloses providing technical support to operating personnel before and/or during the performance of the procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Ramshaw within Hamada, Tubo, and AORN. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(C) Referring to claim 12, Hamada, Tubo, and AORN do not disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Ramshaw within Hamada, Tubo, and AORN. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

11. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of Tubo et al. (5,040,677), and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 14, Alten discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising:

a customized allograft for a predetermined surgical procedure (abstract and col. 1, lines 45-62 of Alten).

Alten does not disclose arranging for the delivery of the allograft and providing technical support and/or customer support to operating personnel before and/or during the performance of the procedure.

Tubo discloses arranging for the delivery of the allograft (col. 1, lines 27-29 of Tubo).

Ramshaw discloses providing technical support and/or customer support to operating personnel before and/or during the performance of the procedure (col. 2, lines 39-56 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Tubo and Ramshaw within Alten. The motivation for doing so would have been for direct delivery (col. 1, lines 27-29 of Tubo) and to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(B) Referring to claim 15, Alten discloses wherein the allograft is harvested at a tissue bank (abstract of Alten).

Alten does not disclose that the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed.

Tubo discloses that the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed (col. 1, lines 27-29 of Tubo).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Tubo within Alten. The motivation for doing so would have been for the grafts to be ready for application to the patient (col. 1, lines 27-29 of Tubo).

(C) Referring to claim 16, Alten and Tubo do not disclose prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Ramshaw discloses prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (col. 2, lines 39-41 and col. 8, lines 65-67 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Ramshaw within Alten and Tubo. The motivation for doing so would have been to provide interactive training (col. 1, lines 7-10 of Ramshaw).

(D) Referring to claim 17, Alten and Tubo do not disclose wherein the step of providing technical support includes providing for the presence of a trained representative

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knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Ramshaw within Alten and Tubo. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a system and method for automatic shape registration and instrument tracking (US 2002/0087101 A1); a tooth implant and method for implantation (6,089,867); a computer-assisted surgical system (5,682,886); an activity based cost tracking system (5,732,401); a self-aligning bone implant (US 6,447,545 B1), and bone allografts: past, present and future.


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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3-8-06


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER